

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Maryland Board of Pharmacy Deena Speights-Napata, MA, Executive Director 4201 Patterson Avenue Baltimore, MD 21215-2299

July 16, 2020

VIA REGULAR & CERTIFIED MAIL RETURN RECEIPT REQUESTED ARTICLE #: 7018 1130 0002 2824 7138

Allied Pharmaceutical
1201 Seven Locks Road
Rockville, MD 20854

Attn: Steven George, R.Ph., Pharmacy Manager

Re: Permit No. PW0151

Case No. 20-216

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

Dear Pharmacy Manager:

On October 17, 2019, an annual inspection was conducted by the Board of Pharmacy (the "Board") to determine if Allied Pharmaceutical (the "Pharmacy") was in compliance with federal and state laws regarding the operation of a pharmacy. The Inspection Report indicated that the Pharmacy was not in compliance with certain requirements concerning medication inventory. Specifically, the Pharmacy had four (4) boxes with ten (10) vials each of expired medication in the sterile medication storage area. The Board's records indicate that the Pharmacy also had expired medications in its automated medication system as well as sterile medications without labeled expiration dates on its previous annual inspection of May 23, 2018.

I. FINDINGS AND CONCLUSION

The Board finds that the Pharmacy had four (4) boxes with ten (10) vials each of expired medication in its sterile inventory, as specifically set forth in the Inspection Report dated October 17, 2019.

Based upon deficiencies cited at your Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. § 12-403(c)(1) and (12) and COMAR 10.34.12.01B and 10.34.19.05-06.

II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a civil monetary penalty of \$1,000.00. The deficiencies upon which the civil monetary penalty is based are noted above and in the Board's Inspection Report, dated October 17, 2019.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

III. FOLLOW-UP INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to ensure that the deficiencies noted in the Report have not reoccurred. Should the follow-up inspection indicate that the Pharmacy has further deficiencies, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 et seq., and COMAR 10.34.01. Any request for a hearing must be submitted in writing to Donna Goldberg, R.Ph., J.D., Maryland Board of Pharmacy, 4201 Patterson Ave., 5th Floor, Baltimore, Maryland 21215, no later than thirty (30) days from the date of this Notice.

Please be advised that at the hearing the Pharmacy would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on its own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy guilty of the violations cited in the Reports, the Board may suspend or revoke the pharmacy permit, impose civil penalties, or both. If the Pharmacy requests a hearing but fails to appear, the Board may nevertheless hear and determine the matter in the Pharmacy's absence.

V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Pharmacy may pay the recommended civil monetary penalty within thirty (30) days of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy.

Please mail the check or money order to:

Wells Fargo Bank Attn: State of Maryland - Board of Pharmacy Lockbox 2051 7175 Columbia Gateway Columbia, MD 21046

NOTE: Please include the case number, 20-216, on your check or money order to ensure proper assignment to your case.

The Pharmacy shall also submit to the Board a corrective action plan within thirty (30) days of the date of this Notice detailing, at minimum, actions taken to remedy the above labeling and inventory deficiencies.

Upon the Pharmacy's payment of the civil monetary penalty and submission of the corrective action plan, this Notice will constitute the Board's final action and order with respect to the inspection report dated October 17, 2019, and shall be a public document in accordance with the Maryland Public Information Act and posted and reported in accordance with federal and State laws.

If you have any questions concerning the instructions contained in this letter, please contact Donna Goldberg, R.Ph., J.D., at 410-764-3768.

Sincerely.

Deena Speights-Napata, MA

Executive Director